



**United States
Department of
Agriculture**

Food Safety
and Inspection
Service

September 1999

HACCP-12

Generic HACCP Model for Fully Cooked, Not Shelf Stable Meat and Poultry Products

Additional copies of the Guidebook for the Preparation of HACCP Plans and the Generic HACCP Models are available from:

U.S. Department of Agriculture
Food Safety and Inspection Service (FSIS)
Office of Policy, Program Development,
and Evaluation (OPPDE)
Inspection Systems Development Division
Room 202, Cotton Annex Building
300 12th Street SW
Washington, D.C. 20250-3700
Phone: (202) 720-3219
Fax: (202) 690-0824

This material is also available on the FSIS Homepage:
<http://www.fsis.usda.gov/index.htm>



September 8, 1999

TO THE USERS OF THESE VOLUMES

As some of you may know, the Food Safety and Inspection Service (FSIS) received a substantial package of comments on its Guidebook for Hazard Analysis and Critical Control Point (HACCP) Plan Development and the 13 Generic HACCP models, from a coalition of industry and trade associations. This package represents a large and thoughtful effort on the part of these organizations. FSIS intends to give it the careful attention and response that it deserves.

The comments included many technical suggestions for improvements in the FSIS documents. It also included reiteration of longstanding differing policy viewpoints that have been frequently discussed by the Agency and the regulated industry. For the first time, the comments revealed substantially differing expectations on the part of these organizations and FSIS with respect to the purpose of the FSIS documents and their intended use. We want to address some aspects of this latter point.

When the Pathogen Reduction/Hazard Analysis and Critical Control Point systems (PA/HACCP) final regulation was published on July 25, 1996, the DRAFT Guidebook was included as an appendix. The Generic Models, developed for FSIS under contract, were available shortly thereafter in April 1997. It was probably inevitable that there were significant differences between the final regulatory language of CFR Part 417 and the DRAFT Generic Models as they were developed independently. It would have been inappropriate for FSIS to discuss its final regulatory language with any outside group. The contractor was appropriately proceeding from what it knew best, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) documents on the subject of HACCP. Therefore, FSIS accepted that work product with full knowledge that significant revisions would be necessary.

As time passed, FSIS managers became increasingly uncomfortable with the situation in which its major technical assistance documents did not appropriately and completely inform the regulated industry of Agency expectations regarding regulatory compliance. Because the intended audience for these technical assistance materials was primarily the very small establishments, which the Agency believed to have the least HACCP-experience, the Agency began the systematic revision of the documents to overcome this problem. We targeted the summer of 1999 as the completion date for this effort.

FSIS now believes that others had very different ideas about the purpose and use of the documents than it did. As is consistently reiterated in the documents themselves, they are not designed to be used "as is." That is, they cannot be copied and used by an establishment to meet all the regulatory requirements of 9 CFR Part 417. Nor were they designed to be the ultimate teaching and training materials, as some would suggest. The development of ideal generic models is left to others who may have an interest in doing so. The generic models are not

designed to extend or further interpret existing regulations; rather, they are designed to send the user back to the regulations so he/she can become familiar with the requirements as well as the flexibility they permit. The generic models are not designed to present new or alternative methods of producing and processing meat and poultry products. That is also left to others with an interest in doing so.

FSIS envisioned that the generic models might be used in the following way: Suppose a HACCP team leader of a three-person HACCP team in a very small establishment attended a training course, but the others on his/her team were not able to do so. Suppose the HACCP training course met all the requirements of 417.7 but did not provide participants with much in the way of "take away materials" like workbooks, practical questions and answers, access to follow-up resources, etc., which the Research Triangle Institute (RTI) needs assessment indicated were so important to these establishments. The trained HACCP team leader returns to the establishment and begins the process of attempting to develop HACCP plans for the company's products and processes. He/she is quite confident that he/she has grasped the material presented in the training course and begins to work with this team immediately, while the concepts are fresh in his/her mind.

First, he/she has the rest of the team review the Canadian video and the Guidebook from FSIS so that all members of his team have a basic level of information.

The team members begin their work, and as they proceed, some questions arise as to whether what they have developed is appropriate. This is the point when FSIS expects the team to pick up the appropriate generic model and get a sense of whether they are on the right track. They should be able to determine whether the forms that they have developed, while different from the various ones in the generic models and not the same as what other companies use, are acceptable because they include the required information. They will also be able to discover what are some typical food safety hazards that are reasonably likely to occur, as explicitly defined in 417.2, and how to think through the problems that these hazards represent for their own products. They can see how critical limits might arise from existing regulatory requirements like the ones for rapid chilling of poultry products. They can also see that in the absence of settled regulatory requirements, there may be several sources of scientific expertise, and they can choose to make a conservative decision to provide a good margin of safety. They can find out the essential differences between monitoring and verification and have a basis for making their choices about verification activities and their frequencies. FSIS believes that these are useful, beneficial and worthwhile functions for which its generic models can be used.

FSIS is publishing these updated revisions of the generic models, beginning with the Guidebook and the Generic Model for Raw, Ground Product, because a large backlog of requests exists for these two documents. FSIS intends to publish revisions of all the generic models no later than September 30, 1999. Moreover, as a result of public consultation, it may publish an additional revision of some of these models, but given the backlog and the impending HACCP implementation date, we considered it important to get a version of these documents out now.

We hope that these documents are helpful.

Table of Contents

| | |
|--|----|
| Introduction..... | 3 |
| Using This Generic Model..... | 5 |
| Process Flow Diagram and Product Description..... | 6 |
| Hazard Analysis..... | 7 |
| Developing Your HACCP Plan..... | 9 |
| Identifying CCPs..... | 11 |
| Appendix A | |
| References for HACCP Teams | 17 |
| References for Fully Cooked, Not Shelf Stable Meat and Poultry Products.. | 19 |
| Appendix B | |
| Process Flow Diagram (Figure1)..... | 22 |
| Product Description Form (Figure 2)..... | 23 |
| Hazard Analysis Form (Figure 3)..... | 24 |
| HACCP Plan Form (Figure 4)..... | 30 |
| FORM LETTER Confirming <i>Salmonella</i> Compliance with Performance Standards..... | 38 |
| GENERIC ESTABLISHMENT X: MIDSHIFT CLEANUP LOG | 39 |
| THERMOMETER CALIBRATION LOG..... | 40 |
| GENERIC ESTABLISHMENT X: COOLER TEMPERATURE LOG | 41 |

| | |
|--|----|
| GENERIC ESTABLISHMENT X: METAL DETECTION LOG | 42 |
| PRODUCT TEMPERATURE LOG..... | 43 |
| ESTABLISHMENT X: COOKING LOG..... | 44 |
| ESTABLISHMENT X: CHILLING LOG..... | 45 |
| CORRECTIVE ACTIONS LOG..... | 46 |
| PRE-SHIPMENT REVIEW LOG..... | 47 |

GENERIC HACCP MODEL

FOR

FULLY COOKED, NOT SHELF STABLE MEAT AND POULTRY PRODUCTS

Introduction

The Hazard Analysis Critical Control Point (HACCP) system is a scientific approach to process control. It is designed to prevent the occurrence of problems by assuring that controls are applied at any point in a food production system where hazardous or critical situations could occur. Hazards include biological, chemical, or physical contamination of food products.

The Food Safety and Inspection Service (FSIS) published a final rule in July 1996 mandating that HACCP be implemented as the system of process control in all inspected meat and poultry plants. As part of its efforts to assist establishments in the preparation of plant-specific HACCP plans, FSIS determined that a generic model for each process defined in the regulation would be made available for use on a voluntary basis by inspected establishments.

The generic models have been revised since their initial publication and distribution as DRAFTS. The most important change in the revised versions is to make certain that these models are fully consistent with the features of the final regulation. Also, other technical and editorial improvements have been made.

Throughout this generic model, FSIS discusses a HACCP team with members from different departments. In many very small establishments, there will not be separate departments with different employees. But, there will be employees who perform these different functions – often several of them. For purposes of explaining concepts, it is easier to speak as if these were different people, even though in many cases, they may be the same person carrying out more than one responsibility.

Each generic model can be used as a starting point for the development of plant-specific plan(s) reflecting actual plant environments and the processes conducted. The generic model is not intended to be used “as is” for plant specific HACCP plans.

The generic models are designed for use in conjunction with the list of process categories found in the HACCP regulations in section 417.2(b)(1).

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard

analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

- (i) Slaughter--all species: beef, swine, poultry*
- (ii) Raw product—ground: ground beef, ground pork, ground turkey*
- (iii) Raw product--not ground: boneless cuts, steaks*
- (iv) Thermally processed--commercially sterile: canned beef stew, Pasta with meat*
- (v) Not heat treated--shelf stable: summer sausage, dry salami*
- (vi) Heat treated--shelf stable: meat and poultry jerky, snack sticks*
- (vii) Fully cooked--not shelf stable: hot dogs, wieners, roast beef, ham*
- (viii) Heat treated but not fully cooked--not shelf stable: partially cooked patties, bacon*
- (ix) Product with secondary inhibitors--not shelf stable: cured corned beef, cured beef tongue*

This generic model is designed for use with the process category: Fully cooked—not shelf stable.

The purpose of the process category listing in 417.2 is to set out the circumstances under which a HACCP team may develop a single HACCP plan for multiple products. This may be done when products are in the same process category, and food safety hazards, critical control points, and other features are essentially the same. There is a generic model for each process category, plus two for subcategories which present special issues: irradiated products and mechanically separated products.

In order to select the model or models that will be most useful for the activities performed in any specific plant, the following steps should be taken:

- 1) For slaughtering operations, select the model for the appropriate species.
- 2) For processed products, make a list of all products produced in the plant.
- 3) Examine the list and group like products, considering common processing steps and equipment used.

4) Compare the grouped products with the list of processes in the regulations; this step should reveal how many and which of the generic models might be useful.

Deciding on a generic model and which products can be covered by a single plan is an important achievement. If the team does it well, it can save a lot of unnecessary effort and paperwork.

Selecting an inappropriate generic model reduces its potential benefits. However, often the HACCP team will discover they have made this error when they develop their process flow diagram or during their hazard analysis. These are early stages in the process when it is relatively easy to make changes.

In any case, establishments must meet all regulatory requirements for their products.

Using This Generic Model

This generic model is designed to be used by establishments that produce fully cooked, not shelf stable product(s), the seventh process category. The model can be used for all fully cooked, not shelf stable products: either meat or poultry. The generic model is not suitable for products that fall into any of the other process categories.

The model will be most useful to a HACCP team that includes access to one trained individual, as specified in 417.7(b).

(b)The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

It would be beneficial for other team members to have reviewed any of the various guidance materials available on how to develop a HACCP plan for your company, including several useful videos, handbooks, or computer programs. Once the HACCP team has prepared itself as thoroughly as possible in general HACCP principles and how to use them, this model should be helpful.

Note: This generic model includes a number of forms that can be used to record various types of required information. The forms themselves are samples; a company HACCP team can develop whatever forms it finds most useful. All the forms mentioned in this document are included in Appendix B; they appear in the order in which they are discussed in the text.

All FSIS generic models are designed to assist establishments in applying the seven HACCP principles to their meat and poultry processing operations **AND** to meet the regulatory

requirements of Part 417. Therefore, the definitions used in this and all other FSIS generic models are those found in 417.1:

§ 417.1 Definitions.

For purposes of this part, the following shall apply:

Corrective action. *Procedures to be followed when a deviation occurs.*

Critical control point. *A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.*

Critical limit. *The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.*

Food safety hazard. *Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.*

HACCP System. *The HACCP plan in operation, including the HACCP plan itself.*

Hazard. *SEE Food Safety Hazard.*

Preventive measure. *Physical, chemical, or other means that can be used to control an identified food safety hazard.*

Process-monitoring instrument. *An instrument or device used to indicate conditions during processing at a critical control point.*

Responsible establishment official. *The individual with overall authority on-site or a higher level official of the establishment.*

Process Flow Diagram and Product Description

To begin using this model, the company's HACCP team should first describe the product(s) which are part of this process category and covered by this HACCP plan. The product(s) should be described in two ways:

(1) by a simple diagram which shows the steps the company uses when it produces the product, and

(2) in a brief written description which provides key facts about the product and its use.

In this generic model, there is an example for fully cooked, not shelf stable – ham and roast beef. FSIS has developed certain forms as part of the examples in the generic models; **company HACCP teams are not required to use these forms.**

Figure 1 is an example of a **PROCESS FLOW DIAGRAM** for the production of ham and roast beef in generic establishment X. Figure 2 is an example of a **PRODUCT DESCRIPTION** for the ham and roast beef produced in generic establishment X.

Once the company HACCP team in your establishment has prepared your Process Flow Diagram, they should verify it by walking through the establishment following the flow of product and making sure that all the steps of the process are included in the flow diagram. The team should also review the information provided on the Product Description to make sure all the key facts are included, such as identifying consumers, especially those with particular health problems or known to be at risk.

Note: If your process includes steps not included in this example, those steps should be added. Also, if your process does not include all the steps identified in this example, those steps would be omitted when conducting the hazard analysis. That is generally how you use these generic model examples--just omit the features which do not apply to your operation or if your operation includes features not included in this example, they should be added.

By completing a Process Flow Diagram and a Product Description, you have met the requirements of 417.2(a)(2). You can use the Process Flow Diagram in particular to help you complete the rest of the hazard analysis. Use the flow diagram to systematically review each step in the process and ask the question, "Is there a food safety hazard which is reasonably likely to occur which may be introduced at this step?" In answering the question, your HACCP team needs to consider biological (including microbiological), chemical, and physical hazards.

Hazard Analysis

Once your product(s) are accurately described through the flow diagram and product description, the HACCP team should begin work on the **HAZARD ANALYSIS**. The hazard analysis is fundamental to developing a good HACCP plan and one that meets regulatory requirements. The regulatory requirements for a hazard analysis are found at 417.2(a).

§ 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in

the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

Generic establishment X, which we are using for our example, is capturing these regulatory requirements on a 6-column **Hazard Analysis Form (See Figure 3)**. A good way to use a form like this is to create the first column by using the Process Flow Diagram and the second by answering the question. Once the HACCP team has considered all the steps in the flow diagram and determined if a food safety hazard could be introduced, it needs to consider whether the hazard is "reasonably likely to occur", using the meaning of this phrase included in 417.2(a). On the 6-column form used by generic establishment X, the third and fourth columns address this issue. If the establishment's HACCP team has decided that the hazard is not reasonably likely to occur, they enter "No" in column three, explain the basis for their determination in column four, and do not need to further consider activity at this point in the process.

Look at the entries for "Cooking" on the fourth page of the six column form for fully cooked, not shelf stable; the HACCP team has determined that *Listeria monocytogenes*, *Escherichia coli* 0157:H7, *Salmonella*, *Staphylococcus aureus*, and *Trichina* may be present, so it has put a "Yes" in the third column. Column four explains the basis for the team's determination. In the fifth column, the HACCP team has described the preventive measures it will use to make sure that each hazard has been prevented, eliminated, or reduced to an acceptable level. For this hazard, the HACCP team decided that validated time/temperature controls will be verified. FSIS does not consider safe handling labels alone to be an adequate CCP for any pathogenic microorganisms such as bacteria and viruses.

If, however, the team has determined there is a "food safety hazard reasonably likely to occur" introduced at a certain point in the process, column five is used to describe a measure which could be applied to "prevent, eliminate, or reduce to acceptable levels" the food safety hazard identified in column three. Column six is used when a critical control point (CCP) is identified based upon the decision made in the hazard analysis. Each CCP has a number – the order corresponds to steps in the process. For example 1 is the first CCP in the process flow, 2 the next, etc. The letter indicates whether the hazard is biological – B; chemical – C; or physical – P.

Note: Look at the entries for “Storage – (Cold – Frozen/Refrigerated) – Raw Meat” on the second page of the six-column form: the HACCP team has determined that there is a food safety hazard reasonably likely to occur at this step in the process. Column four contains the reason for their thinking: pathogenic organisms can grow in this product if it is not kept sufficiently cool. Column five contains their description of a measure that will prevent the growth of pathogenic organisms: temperatures that are sufficiently low to preclude growth.

You will notice that on our generic hazard analysis for ham and roast beef, there are eight food safety hazards in which the HACCP team has identified a point in the process at which a food safety hazard is reasonably likely to occur. For each one of these they have identified a measure which can be used to control the hazard.

When your HACCP team has completed their hazard analysis (whether they use this format or not), it is a good idea to review the flow diagram, the product description and the hazard analysis itself to make sure they are complete. Part 417.2(a)(3) includes a list of sources from which food safety hazards might be expected to arise. Reviewing that list could help the HACCP team check for completeness.

Note: If you are using this generic model to produce a different fully cooked, not shelf stable product or if you use a different process flow, you may have different hazards which are reasonably likely to occur. For these different hazards, there may be different measures which could be used for control purposes.

This, and all other FSIS generic models, contains a list of references which can help your HACCP team in making sure the hazard analysis is complete. These references are found in Appendix A. A member of your HACCP team might want to review at least some of the references to make sure hazards have not been omitted from the hazard analysis.

Completing the hazard analysis is a very significant and important element in developing your HACCP system. Your HACCP team should feel a real sense of accomplishment when they get this far; this is like completing the foundation of a house.

Developing Your HACCP Plan

The company HACCP team can now take the materials it developed while doing the hazard analysis and use them to build the **HACCP Plan**. Remember that one of the important objectives of the FSIS generic models is to provide examples which illustrate **how to meet the regulatory requirements of Part 417**, as well as to correctly apply the principles of HACCP. Part 417.2 (c) and (d) are the regulatory requirements:

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

- (1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.*
- (2) List the critical control points for each of the identified food safety hazards, including, as appropriate:*
 - (i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and*
 - (ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;*
- (3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;*
- (4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;*
- (5) Include all corrective actions that have been developed in accordance with §417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and*
- (6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.*
- (7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.*
- (d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.*
 - (2) The HACCP plan shall be dated and signed:*
 - (i) Upon initial acceptance;*

(ii) *Upon any modification; and*

(iii) *At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.*

Generic establishment X has prepared its HACCP plan for ham and roast beef on a six column form (See **Figure 4**). You do not need to use this form, although some kind of a form is probably the easiest way to present your HACCP plan.

Identifying CCPs

The first column on this particular form is used to enter information developed and contained on the hazard analysis form. Part 417.2(c)(1) and (2) require that the food safety hazards identified in the hazard analysis be listed on the HACCP plan and that there be a CCP for each identified hazard. You will notice that there were eight points on the hazard analysis form for ham and roast beef where food safety hazards reasonably likely to occur were identified: *Salmonella* on raw meat at receiving, pathogen proliferation at cold storage, pathogen proliferation and metal contamination during preparation of raw meat, pathogen survival, including *Listeria monocytogenes*, at cooking, pathogen proliferation, including *Listeria monocytogenes*, at chilling, contamination with *Listeria monocytogenes* at portioning, and pathogen proliferation, including *Listeria monocytogenes*, at finished product storage (cold). The establishment HACCP team has chosen to have seven CCPs to address these eight hazards: *Salmonella* certification, proper cold storage of raw meat, in-line magnets prior to packaging and labeling, proper time/temperature is reached after cooking is done, proper chilling after cooking, conduct environmental monitoring program for *Listeria spp.*, and proper temperature maintenance at finished product storage (cold).

After identifying its CCPs, the HACCP team proceeded to consider critical limits, monitoring procedures and their frequencies, and verification procedures and their frequencies, and HACCP records.

In deciding what would be the critical limits, the HACCP team first considered whether there were any regulatory requirements which had to be met and would function as critical limits. They did find FSIS regulatory requirements and guidelines for cooking, so they set the critical limit(s) using criteria as specified by FSIS for the control of pathogens.

Once they had decided on their critical limits, they needed to identify how the monitoring procedures would be carried out and at what frequency.

For their cooking step, the establishment had Quality Assurance monitor time/temperature parameters to assure that the critical limit was met and the cooking temperature would be monitored using temperature recording charts for each batch.

These decisions by the HACCP team regarding critical limits, plus monitoring procedures and their frequencies are written up in columns two and three of the HACCP Plan.

The team then went on to consider appropriate verification procedures; the team knew that there were different types of verification and that Part 417.4(a)(2) included specific regulatory requirements for each. The regulatory requirements for ongoing verification are:

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with §417.5(a)(3) of this part.

The HACCP team decided they could verify through the following procedures and frequency:

1. QA supervisor will observe QA technician perform monitoring activities once per shift.
2. Maintenance supervisor will verify the accuracy of the temperature recording charts once per shift.
3. QA will check all thermometers used for monitoring and verification activities for accuracy daily and calibrate to within 2° F accuracy as necessary.

The HACCP team described the verification procedures and their frequencies in the fifth column of their HACCP plan.

The HACCP team for generic establishment X knew that their HACCP Plan needed to provide for a recordkeeping system. They wanted their records to be easy to create and understand. They wanted to be sure their records met regulatory requirements, so they reviewed part 417.5(a) and (b):

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decision making documents associated with the

selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

The HACCP team decided that their records would be kept on some simple forms, some of which the team itself devised.

The HACCP team decided that ten record forms were necessary: Form Letter Confirming *Salmonella* Compliance with Performance Standards, Midshift Cleanup Log, Thermometer Calibration Log, Cooler Temperature Log, Metal Detection Log, Product Temperature Log, Cooking Log, Chilling Log, Corrective Actions Log, and Pre-Shipment Review Log. The forms were designed to provide spaces for all entries necessary for the monitoring and verification activities at the drying step.

On its HACCP Plan, generic establishment X has listed the names of the forms it will be using for monitoring and verification records.

The Corrective Actions Log is used to create the records of any corrective actions taken because of deviations from critical limits at CCPs. On this log, column three references the planned corrective actions for each CCP. The HACCP team carefully reviewed the regulatory requirements for planned corrective actions found at 417.3(a):

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

- (2) The CCP will be under control after the corrective action is taken;*
- (3) Measures to prevent recurrence are established; and*
- (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.*

The HACCP team has developed a specific corrective action plan which will be followed whenever there is a deviation from a critical limit at a CCP; each of the planned corrective actions meets the four regulatory requirements of 417.3(a).

Planned Corrective Actions for CCP 4:

1. QA will segregate and hold all affected product.
2. QA will identify the cause of the deviation and prevent reoccurrence.

The HACCP team also develops planned corrective actions for each of the other CCPs and attaches them to the HACCP plan. Whenever a deviation from a critical limit occurs, company employees follow the corrective action plan and use the Corrective Action Log to create a record of their actions. The Corrective Action Log forms are available at CCPs, so they can be used immediately when an employee performing a monitoring check discovers and records a deviation. All Corrective Action Logs, which have been used during the day, are turned in to the HACCP coordinator.

There is one final verification/recordkeeping requirement which the company must perform; it is found at 417.5(c):

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

In generic establishment X, product is shipped out, often in small lots, throughout the day. This means that pre-shipment verification checks must be as complete as possible when finished product is in storage, so that a shipment can be made up quickly and moved into distribution channels.

The establishment uses a half day lotting system and a midshift cleanup. While the midshift cleanup is being performed, QA personnel or the HACCP coordinator review results of monitoring and verification checks applied to that lot; if there were deviations from critical limits, they review the Corrective Action Logs to make sure all appropriate planned responses were carried out. If everything is in order and there are complete records showing that the establishment has controlled production of this product through its HACCP system, the HACCP coordinator will sign the pre-shipment review form which the HACCP team devised for this purpose.

Note: It is not a regulatory requirement that a separate form be used for pre-shipment review; in addition, FSIS has indicated that it will be very flexible in accepting a variety of arrangements for accomplishing pre-shipment review to reflect the variety of commercial practices which it has encountered in the industry. It is, however, important to remember that pre-shipment review is a regulatory requirement that must be met, as it indicates that the establishment is taking full responsibility for the product having been produced under a well-functioning HACCP system.

The HACCP team believes it has now completed preparation of the documents which are necessary to meet regulatory requirements for a Hazard Analysis and a HACCP Plan for their fully cooked, not shelf stable production process. They have secured a copy of FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to HACCP System Requirements, the HACCP Basic Compliance Checklist which will be used by inspection program personnel. The HACCP team has modified the inspection form to make the statements into positives, and now has a checklist for its own use to make sure they have not omitted anything in their plan development and preparation. When they are confident that they have done what is necessary, they will turn their Hazard Analysis and HACCP Plan over to the establishment owner for decisions about implementation.

APPENDIX A

References for HACCP Teams

1. Agriculture Canada. *Food Safety Enhancement Program – HACCP Implementation Manual*. Camelot Drive, Nepean, Ontario, Canada, 1996.
2. American Meat Institute Foundation. *HACCP: The Hazard Analysis and Critical Control Point System in the Meat and Poultry Industry*. Washington, D.C., 1994.

Useful sections in particular are:

Chapter 3 – microbiological hazards, pp. 15-26

Chapter 4 – chemical hazards, pp. 27-32

Chapter 5 – physical hazards, pp. 33-35

Appendix A – NACMCF HACCP

Appendix C – Model HACCP plans

3. Baker, D.A. *Application of Modeling in HACCP Plan Development*. Int. J. Food Microbiol. 25:251-261, 1995.
4. Corlett, D.A., Jr. and Stier, R.F. *Risk Assessment within the HACCP System*. Food Control 2:71-72, 1991.
5. Council for Agriculture Science and Technology. *Risks Associated with Foodborne Pathogens*. February 1993.
6. Easter, M.C., et al. *The Role of HACCP in the Management of Food Safety and Quality*. J. Soc. Dairy Technol. 47:42-43, 1994.
7. Environmental Protection Agency. *Tolerances for Pesticides in Foods*. Title 40, Code of Federal Regulations, Part 185. U.S. Government Printing Office, Washington, D.C., 1998.
8. Food and Drug Administration. *The Food Defect Action Levels*. FDA/CFSAN. Washington, D.C., 1998.
9. Food and Drug Administration. *Fish and Fishery Products Hazards and Control Guide --Get Hooked on Seafood Safety*. Office of Seafood. Washington, D.C., 1994.
10. International Commission on Microbiological Specification for Foods. *HACCP in Microbiological Safety and Quality*. Blackwell Scientific Publications, Oxford, 1988.

Useful sections in particular are:

Chapter 10 – raw meat and poultry, pp. 176-193

Chapter 11 – roast beef, pp. 234-238

Chapter 11 – canned ham, pp. 238-242

11. International Commission on Microbiological Specification for Foods. *Microorganisms in Foods 4. Application of Hazard Analysis and Critical Control Point (HACCP) Systems to Ensure Microbiological Safety and Quality*. Blackwell Scientific Publications, Boston, 1989
12. National Advisory Committee on Microbiological Criteria for Foods. *March 20, 1992 -- Hazard Analysis and Critical Control Point System*. Int. J. Food Microbiol. 16: 1-23, 1993.
13. National Advisory Committee on Microbiological Criteria for Foods. Adopted August 14, 1997- *Hazard Analysis and Critical Control Point Principles and Application Guidelines*. J. Food Protect. 61(9): 1246-1259, 1998.
14. National Advisory Committee on Microbiological Criteria for Foods. DRAFT document - *FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants*. 1-22, August 1999.
15. National Advisory Committee on Microbiological Criteria for Foods. *June 1993 -- Report on Generic HACCP for Raw Beef*. Food Microbiol. 10: 449-488, 1994.
16. National Research Council. *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*. National Academy Press, Washington, D.C., 1985.

Useful sections in particular are:

Chapter 4 – microbiological hazards, pp. 72-103

Chapter 9 – raw meat, pp. 193-199

Chapter 9 – processed meats, pp. 199-216

17. Notermans, S., et al. *The HACCP Concept: Identification of Potentially Hazardous Microorganisms*. Food Microbiol. 11:203-214, 1994.
18. Pierson M.D. and Dutson, T. Editors. *HACCP in Meat, Poultry, and Fish Processing*. Blackie Academic & Professional. Glasgow, 1995.

Useful sections in particular are:

Chapter 4 – meat and poultry slaughter, pp. 58-71

Chapter 5 – processed meats, pp. 72-107

Chapter 7 – risk analysis, pp. 134-154

Chapter 13 – predictive modeling, pp. 330-354

Fully Cooked, Not Shelf Stable Model

19. Pierson, M.D. and Corlett, D.A., Jr. Editors. *HACCP Principles and Applications*. Van Nostrand Reinhold, New York, 1992.
20. Stevenson, K.E. and Bernard, D.T. Editors. *HACCP: Establishing Hazard Analysis Critical Control Point Programs., A Workshop Manual*. The Food Processors Institute, Washington, D.C., 1995.

Useful sections in particular are:

Chapter 11 – forms for hazard analysis, CCPs, critical limits, HACCP master sheet, example HACCP for breaded chicken

21. Stevenson, K.E. and Bernard, D.T. Editors. *HACCP: A Systematic Approach to Food Safety. 3rd Edition*. The Food Processors Institute, Washington, D.C., 1999.
22. Tompkin, R.B. *The Use of HACCP in the Production of Meat and Poultry Products*. J. Food Protect. 53(9): 795-803, 1990.
23. Tompkin, R.B. *The Use of HACCP for Producing and Distributing Processed Meat and Poultry Products*. In *Advances in Meat Research. Volume 10. Hazard Analysis Critical Control Point in Meat, Poultry and Seafoods*. Chapman & Hall, 1995.

References for Fully Cooked, Not Shelf Stable Meat and Poultry Products

1. American Meat Science Association. *Flowchart for Boneless Ham*. AMSA, Chicago IL, 1995.
2. American Meat Science Association. *Flowchart for restructured roast beef*. AMSA, Chicago, IL, 1995.
3. American Meat Science Association. *Flowchart for cooked sausage*. American Meat Science Association. AMSA, Chicago IL, 1995.
4. Cannon, J. E., et al. *Acceptability and shelf life of marinated fresh and precooked pork*. J. Food Sci. 58: 1249-1253, 1993.
5. Carlier, V., et al. *Heat resistance of Listeria monocytogenes (Phagovar 2389/2425/3274/2671/47/108/340): D- and Z- values in ham*. J. Food Protect. 59: 588-591, 1996.

Fully Cooked, Not Shelf Stable Model

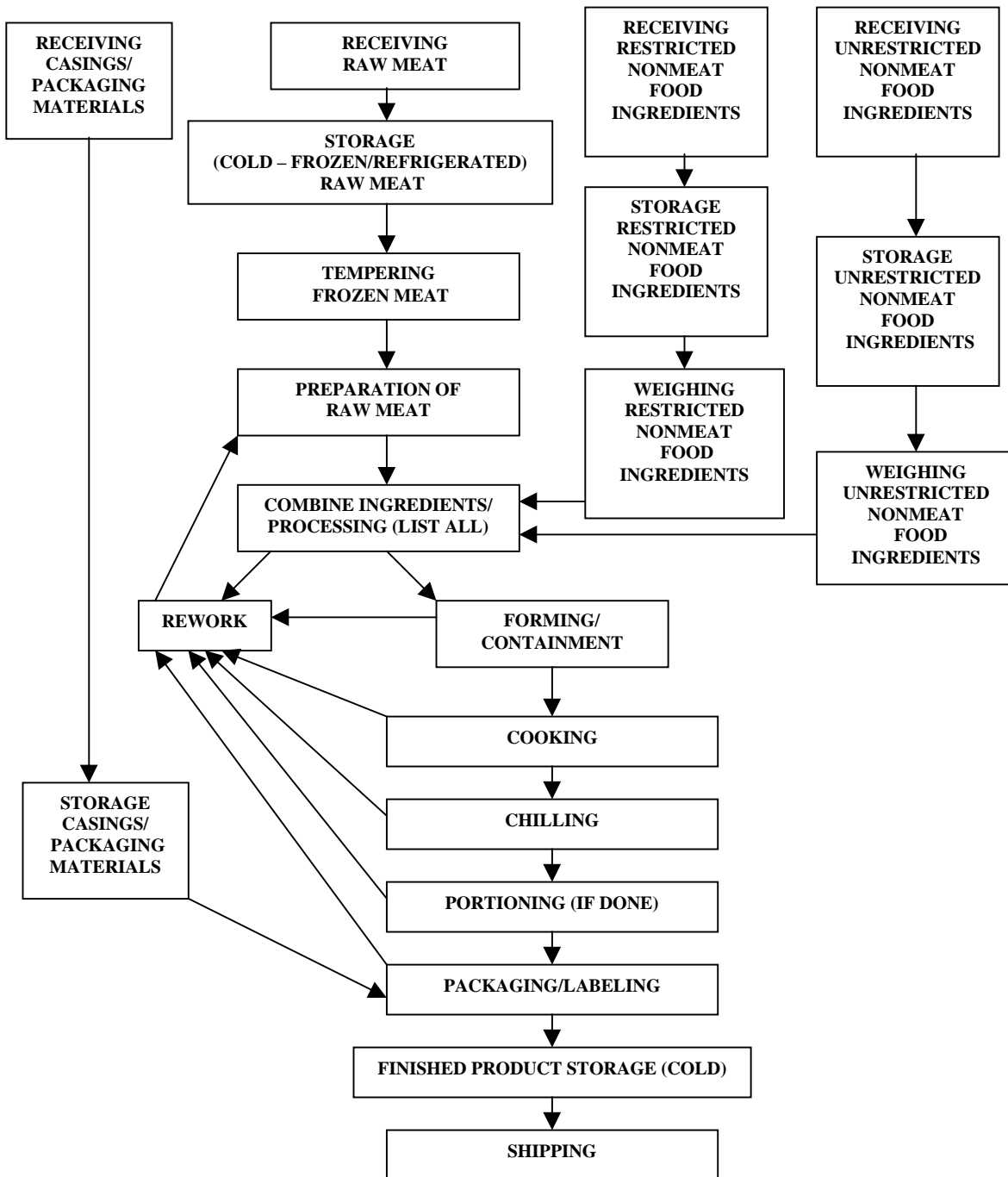
6. Carlier, V., et al. *Destruction of Listeria monocytogenes during a ham cooking process*. J. Food Protect. 59: 592-595. 1996.
7. Cordray, Joseph C., et al. *Restructured pork from hot processed sow meat: effect of mechanical tenderization and liquid smoke*. J. Food Protect. 49: 639-642, 1986.
8. Hudson, J. A., et al. *Growth of Listeria monocytogenes, Aeromonas hydrophila, and Yersinia enterocolitica on Vacuum and Saturated carbon dioxide controlled atmosphere-packaged sliced roast beef*. J. Food Protect. 57: 204-208, 1994.
9. International Commission on Microbiological Specifications for Foods. *Cooking – roast beef (Section 11.5)*. HACCP in Microbiological Safety and Quality. Blackwell Scientific Publications, Oxford, England, pp. 234-238, 1988.
10. International Commission on Microbiological Specifications for Foods. *Curing – perishable canned ham for slicing (Section 11.6)*. HACCP in Microbiological Safety and Quality. Blackwell Scientific Publications, Oxford, England, pp. 238-242, 1988.
11. Kapperud, G. *Yersinia enterocolitica in food hygiene*. Int. J. Food Microbiol. 12: 53-66, 1991.
12. Michel, M. E., et al. *Raw Materials of Cooked Ring Sausages as a Source of Spoilage Lactic Acid Bacteria*. J. Food Protect. 53: 965-968, 1990.
13. Michel, M. E., et al. *Pathogen Survival in Precooked Beef Products and Determination of Critical Control Points in Processing*. J. Food Protect. 54: 767-772, 1991.
14. McDaniel, M.C., et al. *Effect of Different Packaging Treatments on Microbiological and Sensory Evaluation of Precooked Beef Roasts*. J. Food Protect. 47: 23-26, 1984.
15. Papadopoulos, L. S., et al. *Effect of Sodium Lactate on Microbial and Chemical Composition of Cooked Beef during Storage*. J. Food Sci. 56: 341-347, 1991.
16. U. S. Department of Agriculture, Food Safety and Inspection Service. *Generic HACCP Model for Cooked Sausage*. USDA, FSIS. Washington, D.C., 1994.

APPENDIX B

PROCESS FLOW DIAGRAM

Figure 1

PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE PRODUCT: HAM/ROAST BEEF



PRODUCT DESCRIPTION

Figure 2

| | |
|---|--|
| PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE | |
| PRODUCT: HAM, ROAST BEEF | |
| 1. COMMON NAME? | FULLY COOKED HAM A. BONE IN/SEMI-BONELESS B. BONELESS FULLY COOKED ROAST BEEF A. SOLID MUSCLE B. RESTRUCTURED |
| 2. HOW IS IT TO BE USED? (READY TO EAT) | CONSUMED AS PURCHASED |
| 3. TYPE OF PACKAGE? | VACUUM PACKED; HERMETICALLY SEALED; MODIFIED ATMOSPHERE PACKAGING (MAP); OVERWRAP |
| 4. LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE? | VARIES WITH PACKAGING AND STORAGE TEMPERATURE: PREFERRED REFRIGERATED STORAGE TEMPERATURE 30-40°F |
| 5. WHERE WILL IT BE SOLD? CONSUMERS? INTENDED USE? | WHOLESALE TO DISTRIBUTORS ONLY |
| 6. LABELING INSTRUCTIONS? | KEEP FROZEN; KEEP REFRIGERATED |
| 7. IS SPECIAL DISTRIBUTION CONTROL NEEDED? | KEEP FROZEN; KEEP REFRIGERATED |

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE – Ham, Roast Beef

| Process Step | Food Safety Hazard | Reasonably Likely to Occur? | Basis | If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level? | Critical Control Point |
|---|---|-----------------------------|--|---|------------------------|
| Receiving – Raw Meat | Biological: Pathogens <i>Salmonella,</i> <i>Listeria monocytogenes</i> | Yes | <i>Salmonella</i> and <i>Listeria monocytogenes</i> may be present on incoming raw product. | Certification from suppliers that product has met performance standards for <i>Salmonella</i> . During processing, pathogen growth can best be controlled by appropriate cold storage; heat treatment & post heat treatment chilling. | 1B |
| | Chemical – None | | | | |
| | Physical – Foreign materials such as broken needles | No | Plant records show that there has been no incidence of foreign materials in products received into the plant. | | |
| Receiving – Restricted and Unrestricted Nonmeat Food Ingredients; Casings/Packaging Materials | Biological – None | | | | |
| | Chemical – Not acceptable for intended use | No | Letters of guaranty are received from all suppliers of casings/packaging materials. | | |
| | Physical – Foreign materials (wood, metal, glass, etc.) | No | Plant records demonstrate that foreign material contamination has not occurred during the past several years & suppliers have remained consistent. | | |

Figure 3

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

| Process Step | Food Safety Hazard | Reasonably Likely to Occur? | Basis | If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level? | Critical Control Point |
|--|--|-----------------------------|---|--|------------------------|
| Storage – Restricted and Unrestricted Nonmeat Food Ingredients; Casings/ Packaging Materials | Biological – None | | | | |
| | Chemical – None | | | | |
| | Physical – None | | | | |
| Storage (Cold – Frozen/Refrigerated) – Raw Meat | Biological – <i>Salmonella</i> , <i>Listeria Monocytogenes</i> | Yes | Pathogens are reasonably likely to grow in this product if temperature is not maintained at or below a level sufficient to preclude their growth. | Maintain product temperature at or below a level sufficient to preclude pathogen growth. | 2B |
| | Chemical – None | | | | |
| | Physical – None | | | | |

Figure 3

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

| Process Step | Food Safety Hazard | Reasonably Likely to Occur? | Basis | If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level? | Critical Control Point |
|---|---|-----------------------------|---|--|------------------------|
| Tempering Frozen Meat | Biological – Growth of foodborne pathogens | Yes | High temperature during tempering could result in growth of foodborne pathogens. (Recommend surface layer of product (1-inch depth) shall not exceed 40°F for more than 2 hours as part of the tempering procedures for plant operation). | Subsequent cooking step is effective control. | |
| | Chemical – Contamination of product with cleaners, sanitizers, etc. | No | SOPs for sanitation should clearly address prevention of contamination during tempering of meat. | | |
| | Physical | No | Production and process controls to reduce potential contamination | | |
| Weighing Restricted and Unrestricted Nonmeat Food Ingredients | Biological – None | | | | |
| | Chemical – None | | | | |
| | Physical - None | | | | |

Figure 3

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

| Process Step | Food Safety Hazard | Reasonably Likely to Occur? | Basis | If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level? | Critical Control Point |
|--|--------------------------------|-----------------------------|--|--|------------------------|
| Preparation of Raw Meat (including the following; bone-in, semi-boneless, & boneless hams; Solid muscle & restructured roast beef – injection, tumble, massaging, mechanical tenderization, trimming) | Biological– <i>Salmonella</i> | Yes | Prolonged exposure to high ambient temperatures may result in unacceptable levels of pathogens. Potential for cross contamination. | Subsequent cooking step will eliminate this hazard. | |
| | Physical – None | | | | |
| | Physical – Metal Contamination | Yes | Plant records show that during mechanical processing metal contamination is likely to occur. | Metal detector with functioning kick out is installed prior to packaging. | |
| Rework | Biological – Pathogens | No | Rework at the end of the day is condemned. | | |
| | Chemical – None | | | | |
| | Physical – None | | | | |
| Combine Ingredients | Biological – None | | | | |
| | Chemical – None | | | | |
| | Physical – None | | | | |

Figure 3

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

| Process Step | Food Safety Hazard | Reasonably Likely to Occur? | Basis | If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level? | Critical Control Point |
|---------------------|---|-----------------------------|--|--|------------------------|
| Forming/Containment | Biological – None | | | | |
| | Chemical – None | | | | |
| | Physical – None | | | | |
| Cooking | Biological – Pathogens <i>Listeria monocytogenes</i> , <i>Escherichia coli</i> <i>O157:H7</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Trichina</i> | Yes | Potential survival and/or growth of pathogens with the failure of the cooking. | Cook product using validated time/temperature controls. | 3B |
| | Chemical – None | | | | |
| | Physical – None | | | | |
| Chilling | Biological – Pathogens <i>Clostridium perfringens</i> <i>Clostridium botulinum</i> growth & toxigenesis | Yes | Heat shocked <i>Clostridium</i> spores will become vegetative cells that proliferate. Subsequent toxigenesis in the intestine (<i>Clostridium perfringens</i>) or in the food (<i>Clostridium botulinum</i>) possible. | Proper chilling procedures are used. | 4B |
| | Chemical – None | | | | |
| | Physical – None | | | | |

Figure 3

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

| Process Step | Food Safety Hazard | Reasonably Likely to Occur? | Basis | If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level? | Critical Control Point |
|---------------------------------|---|-----------------------------|--|--|------------------------|
| Portioning (If done) | Biological –Pathogens <i>Listeria monocytogenes</i> | Yes | Potential contamination from environmental sources. | Plant will conduct midshift cleanup for each shift using a sanitizer demonstrated effective against <i>Listeria</i> on all product contact surfaces. | 5B |
| | Chemical – None | | | | |
| | Physical – None | | | | |
| Packaging/Labeling | Biological – None | | | | |
| | Chemical – None | | | | |
| | Physical – Metal contamination | Yes | Plant records show that during mechanical processing metal contamination is likely to occur. | Metal detector with functioning kick out is installed prior to packaging. | 6P |
| Finished Product Storage (Cold) | Biological – Pathogens <i>Listeria monocytogenes</i> | Yes | Psychrophilic pathogens are reasonably likely to grow if temperature is not maintained at or below a level sufficient to abate their growth. | Maintain product temperature at or below a level sufficient to abate psychrophilic pathogen growth. | 7B |
| | Chemical – None | | | | |
| | Physical – None | | | | |
| Shipping | Biological – None | | | | |
| | Chemical – None | | | | |
| | Physical – None | | | | |

Figure 3

| HACCP PLAN | | | | | |
|--|---|--|--|---|---|
| PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE | | | | | |
| PRODUCT EXAMPLE: HAM, ROAST BEEF | | | | | |
| CCP# and Location | Critical Limits | Monitoring Procedures and Frequency | HACCP Records | Verification Procedures and Frequency | Corrective Actions |
| 1B Receiving – Raw Meat | Supplier certification that product meets <i>Salmonella</i> performance standards and meets other establishment specifications must accompany shipment. | Receiving personnel will check each shipment for certification. | Receiving Log Corrective Action Log | Every two months QA will request FSIS <i>Salmonella</i> data results from the company for at least 2 suppliers. | Will not receive product unaccompanied by <i>Salmonella</i> certification. If company fails to meet FSIS <i>Salmonella</i> performance standards, it will be an ineligible supplier until standards are again met. |
| 2B Storage (Cold– Frozen/ Refrigerated – Raw Meat | Raw product storage areas shall not exceed 40° F in refrigerated rooms or exceed 28° F in freezer rooms. | Maintenance personnel will check raw product storage area temperature every 2 hours. | Room Temperature Log Thermometer Calibration Log Corrective Action Log | Maintenance supervisor will verify accuracy of the Room Temperature Log once per shift. QA will check all thermometers used for monitoring and verification for accuracy daily and calibrate to within 2° F accuracy as necessary. | QA will reject or hold product dependent on time and temperature deviation. Processing Authority or pathogen growth modeling curves can be used to make a determination. QA will identify the cause of the deviation and prevent reoccurrence. QA will assure that no product that may be adulterated has entered commerce. |

Signature: _____

Date: _____

Figure 4

| HACCP PLAN | | | | | |
|--|---|---|--|---|--|
| PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE | | | | | |
| PRODUCT EXAMPLE: HAM, ROAST BEEF | | | | | |
| CCP# and Location | Critical Limits | Monitoring Procedures and Frequency | HACCP Records | Verification Procedures and Frequency | Corrective Actions |
| 3B Cooking (Ham) | <p>Internal temperature 158°F instantaneously.</p> <p>Time and temperature sufficient to achieve > 7 log reduction in <i>Salmonella</i> as indicated in validated time/temperature tables.</p> | <p>QA will monitor time/temperature parameters to assure that critical limit was met.</p> <p>Continuous temperature recording chart for each batch.</p> <p>At the end of cooking, the internal temperature of product from the coolest part of the cooker will be taken and recorded by QA.</p> | <p>Time/Temperature Log</p> <p>Temperature Recording Charts</p> <p>Product Temperature Log</p> <p>Thermometer Calibration Log</p> <p>Corrective Action Log</p> | <p>QA supervisor will observe QA technician perform monitoring activities once per shift.</p> <p>Maintenance supervisor will verify accuracy of the temperature recording charts once per shift.</p> <p>QA will check all thermometers used for monitoring and verification for accuracy daily and calibrate to within 2°F accuracy as necessary.</p> | <p>QA will segregate and hold all affected product. Processing Authority or expert consultant will advise plant about product deviation; on the basis of this advice product will be recooked or condemned.</p> <p>QA will identify the cause of the deviation and prevent reoccurrence.</p> <p>Maintenance will review operation of the smokehouse and make repairs if necessary.</p> <p>Cold spots will be detected and product temperature determined on these additional points.</p> |

Signature: _____

Date: _____

Figure 4

| HACCP PLAN | | | | | |
|--|--|---|---|---|---|
| PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE | | | | | |
| PRODUCT EXAMPLE: HAM, ROAST BEEF | | | | | |
| CCP# and Location | Critical Limits | Monitoring Procedures and Frequency | HACCP Records | Verification Procedures and Frequency | Corrective Actions |
| 3B Cooking (Roast Beef) | Internal temperature must reach 144°F minimum for 5 minutes. (Time and temperature sufficient to achieve > 7 log reduction in <i>Salmonella</i> as indicated in validated time/temperature tables.) | QA will monitor time/temperature parameters to assure that critical limit was met. Continuous temperature recording chart for each smokehouse will be initialed for each batch. At the end of cooking, the internal temperature of product from the coolest part of the cooker will be taken and recorded by QA. The time the temperature was sustained will be recorded. | Time/Temperature Log Temperature Recording Charts Product Temperature Log Thermometer Calibration Log Corrective Action Log | QA supervisor will observe QA technician perform monitoring activities once per shift and will observe QA taking internal temperature and sustained time once per day. Maintenance supervisor will verify accuracy of the temperature recording charts once per shift. QA will check all thermometers used for monitoring and verification for accuracy daily and calibrate to within 2° F accuracy as necessary. | QA will segregate and hold all affected product. QA assures that the cause of the deviation is identified and the product reworked or condemned according to Process Authority recommendations. Smokehouse or water cook will be adjusted or repaired and the maintenance schedule reviewed or revised as necessary. Cold spots if found will be monitored and product temperature checked from each lot prior to release. |

Signature: _____

Date: _____

Figure 4

Fully Cooked, Not Shelf Stable Model

| HACCP PLAN | | | | | |
|---|---|--|--|---|--|
| PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE | | | | | |
| PRODUCT EXAMPLE: HAM, ROAST BEEF | | | | | |
| CCP# and Location | Critical Limits | Monitoring Procedures and Frequency | HACCP Records | Verification Procedures and Frequency | Corrective Actions |
| 4B Chilling (Ham) | Product to cool from 120°F to 55°F in no more than 6 hours. Chilling begins within 90 minutes; 120°F to 55°F within 6 hours, chilling to continue to 40°F. | QA technician will observe chilling handling procedures to ensure critical limits are met. Cooler temperature will be monitored and recorded continuously using temperature record charts. Time/Temperature will be recorded every 2 hours for each lot until 55°F is reached. QA technician will select and check 5 samples per batch to ensure chilling time/temperature requirements have been met. | Cooler Temperature Recording Chart Product Chilling Log Thermometer Calibration Log Corrective Action Log | QA supervisor will review the product chilling log and cooler temperature recording chart once per shift. Maintenance supervisor will verify the accuracy of the cooler temperature recording chart once per shift. QA will check all thermometers used for monitoring and verification activities for accuracy daily and calibrate to within 2° F accuracy as necessary. | QA will reject or hold product dependent on time and temperature deviation. Process Authority recommendations will be followed if product is not condemned. QA will identify the cause of the deviation and prevent reoccurrence. Cooling maintenance will be verified and any necessary repairs made. |

Signature: _____

Date: _____

Figure 4

| <p style="text-align: center;">HACCP PLAN</p> <p>PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE</p> <p>PRODUCT EXAMPLE: HAM, ROAST BEEF</p> | | | | | |
|--|--|---|--|---|---|
| CCP# and Location | Critical Limits | Monitoring Procedures and Frequency | HACCP Records | Verification Procedures and Frequency | Corrective Actions |
| 4B Chilling (Roast Beef) | Product will be chilled from 120°F to 55°F in no more than 6 hours | QA technician will observe chilling procedures to ensure critical limits are met. Cooler temperature will be monitored & recorded continuously using temperature record charts. Charts will be reviewed for each product lot with time of observation recorded & initialed every 2 hours. QA technician will select & check 5 samples per batch to ensure chilling time & temperature requirements have been met every 2 hours until 55°F internal temperature is reached.. | Cooler Temperature Recording Chart Product Chilling Log Thermometer Calibration Log Corrective Action Log | QA supervisor will review the product chilling log and cooler temperature recording chart once per shift. Maintenance supervisor will verify the accuracy of the cooler temperature recording chart once per shift. QA will check all thermometers used for monitoring and verification activities for accuracy daily and calibrate to within 2° F accuracy as necessary. | QA will reject or hold product dependent on time and temperature deviation. Product disposition based on advice of Processing Authority. QA will identify the cause of the deviation and prevent reoccurrence. Cooler maintenance schedule will be reviewed and any necessary repairs made. |

Signature: _____

Date: _____

Figure 4

| HACCP PLAN | | | | | |
|--|--|---|---|---|---|
| PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE | | | | | |
| PRODUCT EXAMPLE: HAM, ROAST BEEF | | | | | |
| CCP# and Location | Critical Limits | Monitoring Procedures and Frequency | HACCP Records | Verification Procedures and Frequency | Corrective Actions |
| 5B Portioning | No <i>Listeria monocytogenes</i> on product contact surfaces | Cleaning crew supervisor will verify that sanitizer of demonstrated effectiveness against Lm is used on all product contact surfaces at midshift clean up & record results in the midshift cleanup log. | <i>Listeria</i> Sampling Log Corrective Action Log Midshift Cleanup Log | QA will observe cleaning crew supervisor; review log results, and once per week QA will verify that appropriate sanitizer is used according to manufacturer's instructions. | QA will address positive <i>Listeria</i> samples as detailed in the FSIS issuance " <i>Listeria</i> Guidelines for Industry". Midshift procedures will be revised. All products back to last cleanup will be held. No adulterated product will be shipped. |
| 6P Packaging | No metal fragments greater than 1/32 inch. | All product will be visually examined prior to packaging after slicing. | Metal Detection Log | QA will observe packaging personnel perform visual observation and verify the entries in the log. | If metal is found, all product held for examination using metal detector. Cause of deviation is to be determined and appropriate action to prevent recurrence instituted. |

Signature: _____

Date: _____

Figure 4

| HACCP PLAN | | | | | |
|---|---|--|--|---|---|
| PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE | | | | | |
| PRODUCT EXAMPLE: HAM, ROAST BEEF | | | | | |
| CCP# and Location | Critical Limits | Monitoring Procedures and Frequency | HACCP Records | Verification Procedures and Frequency | Corrective Actions |
| 7B Finished Product Storage (Cold) (Continued on next page) | Finished product storage areas will not exceed 40° F. | Maintenance personnel will monitor finished product storage area temperatures every two hours and records results. | Room Temperature Log Thermometer Calibration Log Corrective Action Log | Maintenance supervisor will verify the accuracy of the room temperature log once per shift. QA will check all thermometers used for monitoring and verification activities for accuracy daily and calibrate to within 2° F accuracy as necessary. QA will observe maintenance personnel check finished product storage area once per shift. | If a deviation from a critical limit occurs, the following corrective actions will be taken: 1. The cause of the temperature exceeding 40° F will be identified and eliminated. 2. The CCP will be monitored hourly after the corrective action is taken to ensure that it is under control. 3. When the cause of the deviation is identified, measures will be taken to prevent it from recurring e.g., if the cause is equipment failure, the preventive maintenance program will be reviewed and revised, if necessary. |

Signature: _____

Date: _____

Figure 4

| HACCP PLAN | | | | | |
|--|-----------------|-------------------------------------|---------------|---------------------------------------|---|
| PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE | | | | | |
| PRODUCT EXAMPLE: HAM, ROAST BEEF | | | | | |
| CCP# and Location | Critical Limits | Monitoring Procedures and Frequency | HACCP Records | Verification Procedures and Frequency | Corrective Actions |
| 7B Finished Product Storage (Cold) | | | | | 4. If room temperature exceeds the critical limit, the Processing Authority will evaluate the product time/temperature deviation to ensure the present temperature is sufficient to preclude pathogen growth before release for shipment. If the temperature is not sufficient to preclude pathogen growth, re cooking can be considered after computer modeling of <i>Listeria monocytogenes</i> growth in an assumed worst case scenario. |

Signature: _____

Date: _____

Figure 4

Fully Cooked, Not Shelf Stable Model

FORM LETTER Confirming *Salmonella* Compliance with Performance Standards

Date

To: Plant XYZ

This is to confirm results of any *Salmonella* performance standard sample sets completed during the past six months from your establishment listed below.

Thank you.

| Product | Date Results Received | Test Results | Two Consecutive Failed Tests |
|---------|-----------------------|--------------|------------------------------|
| | | | |
| | | | |
| | | | |
| | | | |

| GENERIC ESTABLISHMENT X: MIDSIFT CLEANUP LOG | | | | | | |
|--|------|-----------|-------|--------------------|---------------------|----------------|
| Date | Time | Sanitizer | Shift | Department or Area | Supervisor Initials | QA Verified By |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Fully Cooked, Not Shelf Stable Model

THERMOMETER CALIBRATION LOG

Calibrate to 32⁰ F while thermometer is in slush ice water

| Date | Time | Department or Area | Thermometer ID# | Personal Thermometer Reading | Adjustment Required (Yes or No) | Initials | Comments |
|-------------|-------------|-----------------------------------|------------------------|---|--|-----------------|-----------------|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

- If a thermometer is broken or taken out of service, document this in the comment column.

Reviewed by: _____

Date: _____

Fully Cooked, Not Shelf Stable Model

GENERIC ESTABLISHMENT X: COOLER TEMPERATURE LOG

ROOM: _____ DATE: _____

| TIME | TEMP | Deviation from CL? (Check if yes) | If Yes, Action? | Monitored by: | Verified by: |
|------|------|--------------------------------------|--------------------|---------------|--------------|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

TIME/TEMPERATURE Critical Limit ---- 40°F

Fully Cooked, Not Shelf Stable Model

| GENERIC ESTABLISHMENT X: METAL DETECTION LOG | | | | | | | |
|--|---------|-------|---------|---------------|------|--------------|-------------|
| Date | Product | Lot # | Results | Seeded Sample | Time | Monitored By | Verified By |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

Fully Cooked, Not Shelf Stable Model

PRODUCT TEMPERATURE LOG

CCP: _____

| | Product Temperature | | | | | Operator's Initials/ Time/Date | Verified by: Initials/ Time/Date |
|----------|---------------------|--|--|--|--|--------------------------------------|--|
| Product: | | | | | | | |
| TIME: | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

Critical Limit:

Corrective Action(s):

Fully Cooked, Not Shelf Stable Model

| ESTABLISHMENT X: COOKING LOG | | | | | | | | | | |
|------------------------------|-------|---------------|------------------------|--------------|---------------|------------------------|------------------------|--|--------------|-------------|
| Product | Lot # | Weight (Lbs.) | Date & Cook Start Time | Cooking Unit | Recorder (°F) | | Manual (°F) | Hold for corrective action (Check if Yes) | Monitored By | Verified By |
| | | | | | House Temp. | Internal Product Temp. | Internal Product Temp. | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

CRITICAL LIMIT - Minimum Internal Temperature - (FSIS Food Standards & Labeling Policy Book)

Pre-shipment Review by (Management): _____

Date/Time: _____

Fully Cooked, Not Shelf Stable Model

| ESTABLISHMENT X: CHILLING LOG | | | | | | | | | | |
|-------------------------------|-------|---------------------------|---------------------------|---------------|---------------|------------------------|------------------------|---|--------------|-------------|
| Product | Lot # | Date & Time Cook Finished | Date & Time Chill Started | Chilling Unit | Recorder (°F) | | Manual (°F) | Hold for corrective action. (Check if Yes) | Monitored By | Verified By |
| | | | | | Chiller Temp. | Internal Product Temp. | Internal Product Temp. | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

CRITICAL LIMIT – Start chill within 90 minutes of finishing cook; chill from 120 °F to 55 °F within 6 hours; and 40 °F or less prior to packaging. (9 CFR 318.17)

Pre-shipment Review By (Management): _____

Date/Time: _____

CORRECTIVE ACTIONS LOG

Product: _____

Lot # _____

| CCP | Deviation/ Problem | Corrective Action Procedures/Explain | Disposition of Product | Responsible Person | Date/Time |
|-----|-----------------------|---|---------------------------|-----------------------|-----------|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

SIGNATURE: _____

DATE: _____

| <p style="text-align: center;">PRE-SHIPMENT REVIEW LOG</p> <p>Date: _____</p> | | | | | |
|---|---------------|------------------------------|----------------|---|-------------------|
| PRODUCT | LOT ID | TIME RECORDS REVIEWED | BY WHOM | LOT RELEASED FOR SHIPMENT? SIGNATURE | COMMENTS * |
| | | | | | |
| | | | | | |
| | | | | | |

*Monitoring frequency as per plan; Critical limits met; Certification (if applicable) as per plan; Deviations if occurred were reviewed for appropriate corrective actions; Records complete and accurate.